IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED STATES OF AMERICA ex rel. LAYNE FOOTE, et al., Plaintiffs, v. ASTRAZENECA LP AND ASTRAZENECA PHARMACEUTICALS LP, Defendants.	C.A. No. 1:10-cv-00095 (SLR)

REPLY IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE THIRD AMENDED COMPLAINT PURSUANT TO RULES 8, 9(b), 12(b)(1) &(6)

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I. INTRODUCTION

AstraZeneca's opening Memorandum (D.I. 72, "Mem.") established that Relators' Third Amended Complaint ("TAC") should be dismissed because its allegations are equally (if not more) consistent with lawful activity, and because it does not establish that any allegedly unlawful activity caused the submission of non-reimbursable claims for reimbursement. Relators' Opposition (D.I. 77, "Opp.") concedes that liability under the FCA cannot arise "simply because [AZ] promoted Crestor for uses not approved by the FDA" (Opp. at 2). The TAC acknowledges that liability cannot be established unless a claim is "ineligible for reimbursement, and therefore false" (TAC ¶¶ 97, 115, 119, 170), and Relators' Opposition concedes that any prescription for an on-label or off-label use that is "medically-accepted" is properly reimbursable. Opp. at 5.

Unable to plead facts establishing that AstraZeneca caused the fraudulent submission of claims for non-reimbursable uses, Relators fall back on a theory that "AZ implemented a scheme to steal market share from its established competitors" through false and misleading statements regarding Crestor's safety and efficacy. Opp. at 2, 3-4. According to Relators, "the salient allegation is that AZ used false and misleading statements" to promote Crestor. Opp. at 2. This theory rests entirely on the proposition that any time a physician prescribes a product, "whether for FDA-approved or unapproved uses," based on such statements, any resulting claim for reimbursement is "false within the meaning of the FCA and state analogues" as a matter of law. Opp. at 13; *see also* Opp. at 14 n.7. Thus, Relators' case rises or falls on the premise that "a claim induced through deception is not reimbursable." Opp. at 18. This premise is false, and the TAC should be dismissed with prejudice.

II. ARGUMENT

A. False And Misleading Promotion Without Submission Of A False Claim For A Non-Reimbursable Use Is Insufficient To State An FCA Claim.

While Relators cite various paragraphs in the TAC which purportedly allege "false and misleading statements," they cite nothing which creates a strong inference that false claims were submitted for any non-reimbursable use. Thus, they have failed to plead the "sine qua non" of an off-label FCA claim – "an actual false claim." *See, e.g.*, *United States ex rel. Booker v. Pfizer, Inc.*, 9 F. Supp. 3d 34, 50 (D. Mass. 2014); *see also* Mem. at 11-12. Relators' argument that the use of false and misleading statements "is actionable irrespective of the drug's FDA approval profile" (Opp. at 2), is wrong as a matter of law. Courts have repeatedly rejected the proposition that "false and misleading statements" alone can establish the "false or fraudulent claim" necessary under the FCA. *See Booker*, 9 F. Supp. at 53-54 (rejecting relators' "attempt to establish the falseness of claims derived from fraud as a categorical matter"); *see also* Mem. at 11.

The cases Relators cite for this proposition do not support it.[1] Indeed, *United States ex rel. Franklin v. Parke Davis*, a case cited by Relators (Opp. at 11 n.6), recognized that "the

[1] Unlike the TAC, in *United States ex rel. Franklin v. Park-Davis* and *Strom ex rel. United States v. Scios, Inc.*, relators alleged that that defendant's conduct led to the submission of claims for specific off-label and non-reimbursable uses. *See* 147 F. Supp. 2d 39, at 48 (D. Mass. June 25, 2001) (complaint "describe[s] a scheme of fraud designed to increase the submission of **off-label** prescriptions for Neurontin for payment by Medicaid" (emphasis added)); 676 F. Supp. 2d 884, 886 (N.D. Cal. 2009) ("[T]he material allegations revolve around whether or not Defendants induced doctors to prescribe their drug . . . **for a use that was not medically accepted**." (emphasis added)). The other cases Relators cite do not concern claims premised on false and misleading statements, but rather concern false certification theories of liability. *See United States ex rel. Hutchenson v. Blackstone Med., Inc.*, 647 F.3d 377, 384 (1st Cir. 2011) (FCA liability based on false certification arising from anti-kickback statute violations); *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 780 F.3d 504, 507 (1st Cir. 2015) (alleging FCA liability based on noncompliance with licensure requirements and subsequent reimbursement claims); *United States ex rel. Petratos v. Genentech, Inc.*, No.

alleged FCA violation arises – not from the unlawful marketing activity itself – but from the submission of Medicaid claims for uncovered off-label uses induced by Defendant's fraudulent conduct." 147 F. Supp. 2d at 52 (emphasis added); *see also* Mem. at 12-13.

B. Relators' Allegations Do Not Lead To A Strong Inference That Non-Reimbursable Claims Were Submitted To The Government.

The dispositive issue is whether Relators alleged both a fraudulent scheme and reliable indicia that leads to a strong inference that non-reimbursable claims were actually submitted to the government. *See Foglia v. Renal Venture Mgmt. LLC.*, 754 F.3d 153, 156 (3d Cir. 2014). Not only have Relators failed to raise a strong inference that non-reimbursable claims were submitted, but the TAC fails to allege facts which raise any such inference.

Relators allege various types of "false and misleading statements" about the efficacy and safety of Crestor. However, their Opposition cites nothing from the TAC alleging that these statements caused the submission of non-reimbursable claims, because the TAC contains no such allegations. In fact, Relators' attempt to plead the key element of the FCA is essentially identical for each category of alleged "deception": that "based on these false and misleading representations," identified physicians "wrote Crestor prescriptions, which caused false claims to be submitted to [government programs], which in turn paid at least one false claim." *See* TAC ¶¶ 184-85, 190, 223 (superiority to other brands), 240-42 (ethnic populations), 258, 263-64, 277 (superiority to generics), 300, 307-08, 311, 319 (ASTEROID/regression), 329, 332 (METEOR), 345 (CORONA), 387-89 (JUPITER/primary prevention), 401, 442 (diabetes, "pleiotropic" effects). Nowhere does the TAC allege that any of the identified physicians wrote prescriptions for non-reimbursable uses of Crestor. Rather, the TAC merely alleges that the physicians increased their prescribing of Crestor over other statins. *See* TAC ¶¶ 240, 241, 277, 424.

11-3691, 2014 U.S. Dist. LEXIS 175223, *8-9 (D.N.J. Dec. 18, 2014) (false certification theory).

Indeed, the TAC repeatedly alleges that this was the purpose of the scheme. *See* TAC ¶¶ 186, 190, 195, 225, 240, 246, 262-63, 273, 277, 329. Thus, the upshot of Relators' case is not that physicians wrote prescriptions for non-reimbursable uses, but that they wrote prescriptions for reimbursable uses that would otherwise have gone to one of AstraZeneca's competitors.

Faced with this reality, Relators stand on the faulty legal premise that false or misleading statements alone can establish a false claim. *See supra* II.A; Mem. at 11-13. However, because there is no allegation that reasonably, plausibly or particularly suggests that any alleged false or misleading statements led to the submission of a claim for a non-reimbursable use, the TAC should be dismissed.[2]

Apparently hedging their bet with at least one category of alleged misrepresentation, Relators contend that "the TAC includes detailed allegations that regression is not a reimbursable use of Crestor." Opp. at 21. However, the paragraphs of the TAC Relators cite do not support this contention. Instead, they concern AstraZeneca's policies regarding product promotion (TAC ¶¶ 283-87), clinical studies regarding atherosclerosis (TAC ¶¶ 288-96, 320-26), and AstraZeneca's alleged promotional efforts around those studies (TAC ¶¶ 297-319, 327-35). Relators' assertion that "Crestor prescriptions were written to regress atherosclerosis or prevent heart attacks and strokes, and that associated claims for reimbursement were submitted" (Opp. at 16), is similarly unsupported by the actual allegations in the TAC. The TAC lacks any direct allegation that "Crestor prescriptions were written to regress atherosclerosis or prevent heart

[2] Relators assert that AstraZeneca did "not address a myriad of other allegations . . . likely because AZ must concede they are sufficiently specific and state a claim for relief." Opp. at 17 n. 8. However, the only examples that Relators cite, TAC ¶¶ 224-52 (allegations re: ethnic populations) and TAC ¶¶ 253-82 (allegations re: generic statins) were part of Relators' "superiority" allegations (*see* TAC, Table of Contents) and fail for the same reasons: Relators have not tied alleged false and misleading statements related to the on-label use for ethnic populations or for on-label uses compared to generic statins to the submission of a false claim for a non-reimbursable use.

attacks and strokes," but instead merely states that various physicians "wrote Crestor prescriptions" for unspecified uses. *See, e.g.*, TAC ¶ 300; *see also* Mem. at 15-17.

While Relators contend that "[w]hether the unapproved uses that AZ pushed on physicians overlap with approved uses and patient populations is irrelevant" (Opp. at 2), it is equally plausible that physicians prescribed Crestor for reimbursable uses precisely because of this acknowledged overlap. *See* Mem. at 6-8. Relators assert that the issue cannot be decided at this stage (Opp. at 20-21), but do not actually challenge the conclusion that the scheme alleged in the TAC concerns reimbursable uses of Crestor. *See* Mem. at 16-17. While complex fact issues are not typically decided on a motion to dismiss (Opp. at 20), the law does not prevent dismissal where the reimbursable uses are clear and unchallenged. *See, e.g.*, *Gohil*, 2015 WL 1456664, at *11 (dismissing FCA claims where complaint specifies only off-label uses which were medically accepted indications).

C. Relators' AKS Claims Are Based On Lawful Conduct And Should Be Dismissed.

Relators acknowledge that "it is not unlawful to compensate speakers and consultants for their time." Opp. at 22. At the same time, Relators attempt to save their kickback claims by listing a series of allegations that describe various speaker programs, CME programs and Advisory Boards for which speakers and consultants were lawfully compensated, infusing those allegations with sinister descriptions, and then making the conclusory assertion that such conduct "induce[d]" the writing of Crestor prescriptions. *See* Opp. at 22-23.

Critically, Relators do not contest that physicians were paid fair market value for their services (*see* Mem. at 17-18), or that the services were actually rendered. TAC ¶¶ 446, 451, 453, 454 (conceding that remuneration paid was "in exchange for [physician's] services"). Thus, the activities alleged in the TAC are equally, if not more, consistent with lawful conduct, and

Relators' AKS claims should dismissed. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

D. Relators' Pre-2007 Claims Are Time Barred Because They Relate To A Time Period That Was Not At Issue In The Second Amended Complaint.

Relators argue that the TAC relates back to 2003 because it "describes pre-2007 conduct that was alleged in the SAC." Opp. at 23. This argument does not square with the Second Amended Complaint ("SAC"), which alleged that the scheme began in 2007. *See* SAC ¶ 2. This allegation in the SAC refutes the notion that the SAC gave AstraZeneca notice of claims before this date. *See Glover v. F.D.I.C.*, 698 F.3d 139, 147-48 (3d Cir. 2012) ("Rule 15(c) cannot save a complaint that obscures the factual predicate and legal theory of the amended claim."). Relators cite no authority for the notion that claims from an earlier time period can relate back to a pleading that explicitly did not encompass that same time period. To the contrary, "cases are legion which refuse to allow relation back when the new allegations go beyond the time-frame of the original complaint." *See Quaak v. Dexia*, S.A., 445 F. Supp. 2d 130, 138-39 (D. Mass. 2006) (citing *In re Alcatel Sec. Litig*., 382 F. Supp. 2d 513, 529 (S.D.N.Y. 2005) (refusing to allow relation back when original complaint centered around an IPO and amended complaint concerned behavior prior to the IPO); *In re Bausch & Lomb Sec. Litig*., 941 F. Supp. 1352, 1366 (W.D.N.Y. 1996) (refusing to allow relation back for an amendment concerning a press release prior to the initial class period)).[3]

For these reasons, Relators' pre-2007 claims should be dismissed.

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[3] Relators' Exhibit B does not alter this conclusion. The entries in Exhibit B that Relators label as "repeated" overwhelmingly concern background facts that do not implicate any impermissible conduct and, thus, would not put AstraZeneca on notice of pre-2007 claims. Likewise, the facts in Exhibit B that Relators assert "Relat[e] Back" do not "relate back" to pre-2007 conduct where the SAC specifically alleged that the scheme began in 2007.

E. The Court Should Decline To Exercise Supplemental Jurisdiction Over Relators' State Law Claims.[4]

Relators' argument that even if the Court dismisses the federal FCA claims it should exercise supplemental jurisdiction over Relators' state law claims (*see* Opp. at 24-25) is wrong for several reasons. First, the state law claims fail and should be dismissed for the same reasons as Relators' federal claims. Second, even if the Court found that Relators sufficiently pled a state law claim, cases (including the lone case cited by Relators) have overwhelmingly rejected exercising supplemental jurisdiction over state law claims where the federal claims have been dismissed. *See, e.g., United States ex rel. Digital Healthcare, Inc. v. Affiliated Computer Servs.*, 778 F. Supp. 2d 37, 55 (D.D.C. 2011); *see also* Mem. at 21 (collecting cases). If the Court dismisses the federal claims, it need not and should not assume the burden of managing 28 distinct sets of law and facts – including witnesses and documents specific to each state – particularly where those states themselves have declined to intervene and pursue Relators' allegations. Accordingly, this Court should decline to exercise supplemental jurisdiction.

F. Relator Lorden's Claims Are Barred By The First-To-File Rule.

Relators argue that the "exception-free" language of the first-to-file rule does not apply where new relators voluntarily join a previously-filed suit. *See* Opp. at 26-27. However, Section 3730(b)(5) does not contain an exception for voluntary joinder. Indeed, Relators simply ignore the case law from district courts in this Circuit and nationwide that involves this exact situation. *See* Mem. at 25-26. For example, in *Palladino*, the court dismissed the later-filed relator's claims under the first-to-file bar even though she was voluntarily joined to the amended

[4] With respect to Relators' arguments concerning specific state law issues related to intervention, retroactive application, and standing, AstraZeneca stands on the arguments set forth in its Memorandum of Law. *See* Mem. at 25-26.

complaint. *See Palladino ex rel. United States v. VNA of S. N.J., Inc.*, 68 F. Supp. 2d 455, 460-61 & 479 (D.N.J. 1999).

Relators, instead, seek to rely on *United States ex rel. Precision v. Koch Indus.*, Inc., 31 F.3d 1015 (10th Cir. 1994) and its progeny, which has been roundly criticized for reading into the statute an exception that does not exist. *See United States ex rel. Manion v. St. Luke's Reg'l Med. Ctr., Ltd.*, No. 06-498-S-EJL, 2008 WL 906022, at *7 (D. Idaho Mar. 31, 2008) (declining to follow Precision because it deviates from the plain meaning of the term "intervene" as used in statute); *United States ex rel. Fry. v. Guidant Corp.*, No. 03-0842, 2006 WL 1102397, at *5-6 (M.D. Tenn. Apr. 25, 2006) (declining to follow Precision in favor of "the straightforward, exception-free interpretation of Section 3730(b)(5)"); *see also* John T. Boese, Civil False Claims and Qui Tam Actions, § 4.03[c] (4th ed.).

Aside from the flawed reasoning of Precision and its progeny, there are significant distinctions between those matters and this one. For example, in *United States v. Educ. Mgmt. Corp.*, 817 F. Supp. 2d 433 (W.D. Pa. 2012), the second relator joined the action after the Government elected to intervene and, thus, the court reasoned that, "[a]s a practical matter, the addition of a [second relator] may be of limited impact because the United States has intervened and is vigorously pursuing the case." *Id.* at 459 n.18. Further, *United States ex rel. Boise v. Cephalon, Inc.*, No. 08-287, 2014 WL 5089671, at *2-3 (E.D. Pa. Oct. 9, 2014) relied heavily on policy considerations to allow a later-filed relator to join an earlier action, even though the statutory language is clear. Here, "[t]he statute not only prevents a person from bringing a 'related action' but also from intervening in any way. Adding [a second relator] to the complaint would constitute intervening when using the plain meaning of the term." *Manion*, 2008 WL 906022, at *7.

The plain language of Section 3730(b)(5) bars Relator Lorden from joining an earlier-filed action where he would otherwise be barred if he chose to file separately.

G. Relators' Claims Should Be Dismissed With Prejudice.

Relators assert that, "if required by the Court, they could [] supplement their allegations in order to provide a better factual account," but have failed to provide any particulars of how they would do so. *See* Opp. at 30. Relators' TAC was filed in response to AstraZeneca's prior motion to dismiss, which highlighted the same deficiencies in the Second Amended Complaint. Relators have provided no reason why they would be able to cure these same defects through a fourth amended complaint. Further, another amendment would be futile because no amount of additional allegations can save Relators' legally baseless theory that any claim submitted based on a false and misleading statement violates the FCA.

III. CONCLUSION

For the reasons stated above and as set forth in AstraZeneca's opening Memorandum of Law (D.I. 72), the Court should dismiss the TAC with prejudice.

July 24, 2015

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